

African-American Participation in Clinical Trials: Situating Trust and Trustworthiness

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The concept of trust in the context of race, ethnicity and culture is complex. This article explores biases inherent in our understanding of the dynamics of trust and minority populations. It identifies specific dimensions of trust that may be at play in the research encounter and provides a conceptual framework that may be useful when seeking solutions for improving minority participation in clinical trials.

The National Institutes of Health (NIH) Revitalization Act of 1993 acknowledges that significant gaps in knowledge about health problems affecting minority groups reflect, in part, the inequitable racial and ethnic representation of these populations in clinical research. It seeks to remedy this disparity by mandating that NIH-supported biomedical and behavioral research involving human subjects include recruitment and retention strategies for the inclusion of women and minority groups in grant applications or cooperative agreements.¹ This mandate has stimulated numerous investigations on factors that influence minority participation in research.²⁻²⁷ In turn, these studies attempt to offer investigators and institutions solutions for effective recruitment strategies for increasing the number of subjects from minorities and other under-represented groups in research on disease prevention, treatment, and control.

INHERENT BIASES

Reports on African-American attitudes and perspectives toward clinical research suggest that mistrust is a significant barrier in the accrual of minorities in clinical trials. The United States Public Health Service

(USPHS) Study on Untreated Syphilis in the Negro Male at Tuskegee is often cited as the paradigm case of abuse in medical research and as the exemplar of the source of mistrust among African Americans.^{5,9,19,28,29} Yet, as Gamble writes, problems involving the cultural mistrust between whites and blacks in this country predated public knowledge of the USPHS Syphilis Study.³⁰ She further states that there is a narrowness in emphasizing "...a single historical event to explain deeply entrenched and complex attitudes within the black community." Furthermore, the influence of knowledge of this historical event on subsequent decisions to participate in research is equivocal.^{9, 21, 31, 32} Data from focus groups on African-American participation in research showed that among some participants information about the historical syphilis study did not influence their decisions to participate in subsequent research protocols.^{9, 32}

The literature on minority participation in research often situates trust either in an historical framework, as in the case of Tuskegee, or within a larger sociopolitical context. For example, discussions on conspiracy theories of racial genocide conducted through AIDS research suggest that this view may contribute to African-American mistrust of government institutions.^{5, 9, 18} While these beliefs and concerns may indeed exist among some members of the African-American community, such analyses may promote an unfair portrayal of African Americans as inherently mistrustful. Such stereotypes contribute to negative provider beliefs about the willingness of minority patients to participate in research. This may subsequently influence their decisions to exclude clinically eligible patients from protocols.^{21, 29}

Identifying the locus of mistrust as existing within minorities-framing the issue of trust as something that needs to be cultivated in them-unfairly shifts the burden of change onto these groups. Furthermore, situating problems associated with trust outside of a more local institutional context fails to recognize the influence of the clinical encounter on decision-making. Clinical encounters where patients directly experience actual

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untrustworthy situations are more likely to affect their decision whether or not to participate in research protocols.^{18, 20} It is perhaps more equitable, then, to reframe the discourse on mistrust as the breach of trust. Such a stance may encourage investigators to look within their own research environments and institutional structures as the source of untrustworthiness. In so doing, individuals or institutions involved in designing, implementing, and monitoring research may exercise their responsibility to work toward change.

DIMENSIONS OF TRUST

Without a clear understanding of what is implied by the concept of trust, it is difficult to identify courses of action for its cultivation. Cooper has identified dimensions of trust that correlate with at least three distinct semantic or conceptual frameworks.³³ These include: (a) trusting in the fiduciary relationship; (b) trust as confidence in competence; and (c) perceptions of trustworthiness.

Trust in the fiduciary relationship. This concept of trust recognizes the power differentials that exist in the patient/participant-doctor/investigator relationship. Because of hierarchy of roles, medical illness, or the lack of technical information, all patients and research subjects are vulnerable to varying degrees. As such, patients and subjects are placed in the position of needing to entrust their welfare to physicians, researchers, and institutions with the expectation that decisions and actions with regard to treatment or referrals will be made in their best interest. In an environment where physicians bear multiple clinical, research, and teaching responsibilities, the fiduciary relationship to the patient or research participant may be subject to multiple conflicting interests.^{29,34-36} Members of minority groups may regard such conflicts with suspicion particularly in situations where investigator behaviors seem to convey more "concern about the trial than about the patient."²⁹ Another example of this includes the perception of the process of informed consent as a way to protect hospitals and doctors from legal responsibility.⁵

Trust as confidence in competence. Confidence in the skills and knowledge of physicians or investigators is independent of the recognition of their fiduciary commitments. Standards used for judging competence are highly individual, but may include valuing elite credentials or other external signs of success. Shared ethnicity and culture may foster confidence in a physician's ability to understand patient needs. One study identified concerns by African Americans that "white doctor[s]

might not have the knowledge and understanding of the problems faced by black people from a biological and a life situation perspective."³²

The relationship between confidence in competence and minority participation in research is suggested by one study where African-American patients stated that they were more likely to participate in research if encouraged by medical providers who are viewed as being highly competent.¹⁸ The competence of institutions may also be subject to judgement. For example, "research hospitals" may be seen as having greater expertise in diagnosis and treatment, particularly of rare diseases.⁹

Perception of trustworthiness. The third category of trust refers to the ability to perceive humanistic qualities in the researcher or in the research environment. Virtues such as compassion, altruism, empathy, credibility, honesty or reliability can foster interpersonal trust.³⁷ For example, African-American subjects may be more willing to participate in research if they are referred by medical providers they view as compassionate.¹⁸

The role of communication in developing and maintaining trust is vital to all three categories, but is particularly salient in influencing the perception of researcher trustworthiness. For example, focus group participants in one study described the health care workers that they encountered as rude and impatient-behaviors that did not engender trust.⁹ For the virtues of trustworthiness to be conveyed, providers must communicate verbally and non-verbally in a manner that is both respectful and culturally appropriate. Fostering trustworthiness also requires that researchers and institutions be able to use language that is accessible and meaningful to the patient-particularly in obtaining informed consent-and to make provisions for questions that may arise throughout the duration of the study.^{5, 19}

Last, the motives and intentions of the research protocol itself are subject to interpretation through the lens of trustworthiness. Research that serves to improve the health of minority individuals and communities will generally meet the standards of credibility. Poorly designed studies or those designed to reinforce negative or outdated notions of race or biological differences not only match the criteria of being untrustworthy but are also potentially dangerous in their capacity to perpetuate negative stereotypes.¹⁹

CONCLUSION

In designing research strategies to improve minority

participation, investigators must pay close attention to factors relating to trust and trustworthiness. Approaches that situate the problems of mistrust solely within a historical or sociopolitical context may fail to address barriers that currently exist in their own practices and institutions. Minorities should not be considered inherently mistrustful, even if the mistrust can be justified by injustices and disparities in access and care. Such characterizations may create provider bias that, in turn, creates major barriers for referral and compliance in clinical trials. Rather than locating the source of mistrust within minorities, a more equitable stance would include reframing the problem as breeches of trust. This approach invites researchers to search for sources of untrustworthiness among their own practices and behaviors as well as within institutional structures.

Last, without a clear understanding of what is implied by the concept of trust, it is difficult to identify courses of action for its cultivation. Investigators need to be clear in conveying the nature of their responsibilities to patients, research subjects or institutions. This will allow patients to make informed decisions whether or not to entrust their welfare in the relationship with a provider or researcher. The cultivation of a community of skilled and knowledgeable clinicians and investigators can increase confidence in the competence of the research. As the determination of competence can be based on subjective measures, patients and participants can be asked about the criteria they use to trust in the capacities of providers and institutions. This can guide in the development of recruitment and retention strategies. Research should be conducted in a manner that conveys humanistic concerns, including compassion, empathy and honesty. Communication skills, particularly those that foster cultural competence and sensitivity, can serve to encourage provider and institutional trustworthiness.

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